Message

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Subject: FYI. Inside EPA on the OMB/OIRA memo

https://insideepa.com/tsca-news/critics-hope-biden-eos-override-trump-push-omb-review-iris-drafts

Critics Hope Biden EOs Override Trump Push For OMB To Review IRIS Drafts
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The Trump administration's controversial 11th-hour push to again subject EPA chemical assessments to White House review appears to have stalled when a key memo went unsigned, though critics also hope the policy will be overridden by President Joe Biden's early executive order (EO) on modernizing regulatory review.

In a Jan. 8 memo, obtained by Inside TSCA, then-Office of Information and Regulatory Affairs (OIRA) Administrator Paul Ray directed then-EPA Administrator Andrew Wheeler to place chemical assessments from the agency's influential Integrated Risk Information System (IRIS) and other programs under OIRA regulatory review.

"I have determined that IRIS Assessments qualify as 'guidance documents' within the meaning of E.O. [13891] and that certain of these Assessments historically have qualified, and are likely to continue to qualify, as 'significant' as that term is defined in E.O. 12866 and E.O. 13891," Ray writes.

"Under the terms of both of these Orders, therefore, 'draft' and 'final' IRIS Assessments should be submitted to OIRA for determination of significance and, for Assessments deemed significant, for interagency review."

Reports of the memo drew concerns in the final days of the Trump administration as officials appeared to subject a controversial draft assessment of a per- and polyfluoroalkyl substance (PFAS), known as PFBS, to the review requirements, sparking fears that it could renew OIRA reviews of EPA chemical assessments.

But the memo Inside TSCA obtained is not signed, suggesting the policy change was never formalized and thus did not extend past Ray's resignation at the end of the Trump administration.

"If it didn't get finished before [Jan. 20 at] noon, it's finished," James Goodwin, interim executive director of the Center for Progressive Reform, tells Inside TSCA.

Betsy Southerland, a former top EPA official who now works with the Environmental Protection Network of EPA alumni, also believes that even if Ray's directive somehow managed to take effect without a signature, Biden effectively nullified the Jan. 8 memo when he ordered OMB and OIRA to "modernize" their regulatory reviews.

Biden's Jan. 20 order directs OMB to recommend ways "to improve and modernize regulatory review . . . the recommendations 'should provide concrete suggestions on how the regulatory review process can promote public health and safety, economic growth, social welfare, racial justice, environmental stewardship, human dignity, equity, and the interests of future generations.'"

Southerland says the order "should ensure that memo never gets implemented," Southerland tells Inside TSCA. "There is no justification for the OMB memo stating that the predominantly non-scientists in OIRA will decide how to resolve other agencies disagreeing with EPA's IRIS and [some other risk values] which are strictly health-based values."

Goodwin adds that under the order, "one of the things that needs to be considered as part of that broader modernization effort is the proper role of OIRA with regard to agency science. Of course, the only proper role is no role at all. That's where the Biden administration should land, which would make review of these IRIS assessments verboten."

Goodwin, however, acknowledges that there is a risk that a memo like this could slip through the modernization process if it is focused at too high a level. "That's especially a risk because OIRA's career staff have an ideological commitment to meddling in everything agencies do to in order to weaken or block those actions," he says, pointing to former Obama rules chief Cass Sunstein's tenure as an example.

Goodwin is optimistic, however, that Sharon Block, Biden's pick to lead OIRA, will be more engaged. "Sharon Block in particular is well attuned to the dangers of OIRA meddling in agency science. I would expect her to take special care in ensuring that this does not happen on her watch."

OIRA Reviews

Ray's memo argues that "IRIS Assessments and related documents can trigger any number of 'significant' factors under section 3(f)" of President Bill Clinton's E.O. 12866 that first set out what is now the traditional process of White House regulatory review and cost-benefit analysis for "significant" agency actions.

Ray points to IRIS assessments' annual effect on the economy; "potential to create a serious inconsistency or otherwise interfere with an action taken or planned by another agency" and their frequent commentary on novel scientific areas as evidence of their significance.

Had the memo been implemented, it would have revived the ponderous process of OIRA-managed IRIS reviews implemented under the George W. Bush administration, which generally sought to curb the agency's ability to issue risk assessments that could tighten or increase environmental regulations.

Industry and other regulated entities, including the Defense and Energy Departments, have long criticized IRIS' often stringent approaches and risk estimates, arguing that they were overly strict and would result in unnecessarily onerous regulations, and favored IRIS review as one approach to curbing them.

But the Bush-era process was roundly criticized by the Government Accountability Office in a 2008 report, and the Obama administration recrafted the IRIS process in 2009, cutting OIRA out of its gatekeeper role in interagency reviews.

The Jan. 8 memo also sought to expand OIRA's scrutiny beyond IRIS to other types of EPA chemical assessments -- though it does not mention the chemical evaluations that EPA's toxics office is conducting under the revised Toxic Substances Control Act (TSCA), the program the Trump administration sought to subordinate IRIS to.

Instead, the memo names another set of evaluations generally conducted within the same EPA research center as IRIS, known as provisional peer-reviewed toxicity values (PPRTVs). EPA's research office develops PPRTVs for its Superfund office with the aim of providing risk estimates for cleanups, with lesser levels of public scrutiny and peer review that allow the toxicity values to be completed faster than full IRIS assessments.

"This determination applies to EPA health-based values used in lieu of IRIS values; for example, [PPRTVs] that may be reasonably anticipated to be used in the context of contaminant cleanup under CERCLA/RCRA, local or state health-based decision-making, or private sector decisions," the memo states. "Guidance to the public or internal to EPA but affecting the behavior of the public regarding the development, application, or use of these IRIS or PPRTV values would also qualify as guidance."

PFAS Assessment

Even if it was never signed, Ray's Jan. 8 memo was apparently the impetus for an unusual chemical assessment that underwent an even more unusual four-day OIRA review in the final days of the Trump administration -- far shorter than the usual months-long process for draft regulations.

The assessment, of human health toxicity values for a per- and polyfluoroalkyl substance (PFAS) known as perfluorobutane sulfonic acid (PFBS), began OIRA review on Jan. 11, cleared the office Jan. 15 and EPA finalized it on Jan. 19.

The document deviates from long-standing agency guidance and practice in several ways, including by giving risk managers more leeway on how to apply the agency's risk estimates, which observers say could set a permanent precedent on how such evaluations are used.

Southerland told Inside TSCA at the time that the document sets reference doses (RfDs) -- the maximum amount EPA estimates can be ingested daily over a lifetime without experiencing related health effects -- as a range, rather than the customary single point estimate, giving risk managers in industry or state and local governments more freedom to choose which point in that range to use when they set limits on PFBS.

"It's not the numerical difference, it's the principle of this thing -- forever more EPA is going to do ranges for RfDs," Southerland said. "We've lost the ability to be the final decision [maker] about how toxic a chemical is. [With this precedent, that decision is] left to states, private companies, whoever is going to use this value on their own," she said -- Maria Hegstad (mhegstad@iwpnews.com)

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